

It was alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since those which appeared on the label did not provide for sufficient medication to constitute a treatment for gout. (2) In that [its labeling failed to bear adequate warnings] since it was a laxative and the label failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives. (3) In that the statement "Tonic * * * An Allestial Treatment Useful in * * * Gout" was false and misleading since the tablets when used as directed did not constitute a tonic or treatment for gout.

On June 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

763. Misbranding of solution of citrate of magnesia. U. S. v. 144 Bottles of Solution Citrate of Magnesia U. S. P. Default decree of condemnation and destruction. (F. D. C. No. 7397. Sample No. 79270-E.)

On April 27, 1942, the United States attorney for the Southern District of Indiana filed a libel against the above-named product at Richmond, Ind., alleging that it had been shipped in interstate commerce on or about January 26, 1942, by Gordon Pharmacal Co. from Cincinnati, Ohio; and charging that it was misbranded in that it was a laxative and its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use of a laxative might result in dependence upon laxatives to move the bowels.

On June 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

764. Misbranding of Pond's Digestans and Pond's Laxative Pills. U. S. v. 12 Dozen, 4 Dozen, and 1 Dozen Tins of Pond's Digestans. Default decree of condemnation and destruction. (F. D. C. No. 6538. Sample No. 74170-E.)

The labeling of these products failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users, and did bear false and misleading therapeutic claims. The labeling also failed to state the common or usual names of the active ingredients of the laxative pills.

On December 19, 1941, the United States attorney for the District of New Jersey filed a libel against 12 dozen 15-cent, 4 dozen 35-cent, and 1 dozen 65-cent-sized tins of Pond's Digestans, each tin containing a number of brown-coated tablets and a small envelope containing 3 pink pills, labeled "Pond's Laxative Pills," at Newark, N. J., alleging that the articles had been shipped in interstate commerce on or about October 8 and November 13, 1941, by Pond Pharmacal Co., Inc., from New York, N. Y.; and charging that they were misbranded.

Analyses of samples showed that Pond's Digestans tablets consisted essentially of sodium bicarbonate, extracts of laxative plant drugs (including aloin), peppermint oil, and strychnine sulfate; and that the laxative pills consisted essentially of laxative plant drugs (including aloin and podophyllin), and small quantities of belladonna.

The articles were alleged to be misbranded: (1) In that the directions for use appearing on the tins and in the circulars were inappropriate and inadequate for a laxative since they provided for continued administration, which might result in dependence upon a laxative. (2) In that although the labeling cautioned the user against the use of laxatives in the presence of nausea, vomiting, and abdominal pain, it failed to warn that such symptoms may be those of appendicitis; and the tablets contained strychnine but the labeling failed to warn that not more than the recommended dosage should be taken and that its use by children and elderly persons might be especially dangerous. (3) In that the warnings required by law had not been placed upon the labeling with such conspicuousness as compared with other words and statements as to render them likely to be read or understood by the ordinary individual under customary conditions of purchase and use since the warning that did appear was in very small type and at the bottom of the first page of the circular enclosed in the tin. (4) In that the following statements in the labeling, "Digestans * * * These tablets * * * have been found of great value * * * in relieving * * * wind colic. * * * contain bitter stomach tonics used to stimulate the flow of gastric juices. * * * Oil of Peppermint is * * * stimulant to the appetite * * * Gentian is a stimulant to the appetite and is the most popular of all the bitters for its stomachic action. Ipecac in small doses is a carminative, stimulates the appetite and helps the action of the other ingredients. * * * Rhubarb is also a widely prescribed remedy as a * * * bitter," were false and misleading since the name "Digestans" created the impression

that the article so designated was a digestant of food, and the statements created the impression that Digestans would relieve wind colic, that it contained bitter stomach tonics which would stimulate the flow of gastric juices and that the ingredients named would accomplish the individual effects claimed for them; whereas Digestans was not a digestant of food, it would not relieve wind colic, it did not contain bitter stomach tonics that would stimulate the flow of gastric juices, and it would not accomplish the results attributed individually to oil of peppermint, gentian, ipecac, and rhubarb. (5) In that the outside container did not bear an accurate statement of the quantity of the contents with respect to Pond's Laxative Pills. (6) In that the tin and glassine envelope did not bear the common or usual names of the active ingredients of Pond's Laxative Pills.

On May 8, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

765. Misbranding of My-X-Ym. U. S. v. 28 Packages of My-X-Ym. Default decree of condemnation and destruction. (F. D. C. No. 7380. Sample No. 23391-E.)

On April 27, 1942, the United States attorney for the Northern District of California filed a libel against 28 packages of My-X-Ym at Salinas, Calif., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by My-X-Ym Food Enzymes Products from Chicago, Ill.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of ground senna pods, powdered milk, yeast, wheat bran, cornstarch, cacao powder, soybean tissues, and sugars including dextrose and sucrose.

The article was alleged to be misbranded: (1) In that its labeling failed to bear adequate warnings since it was a laxative and the label failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and that frequent or continued use of a laxative may result in dependence upon a laxative to move the bowels. (2) In that the directions which appeared in the labeling provided for continuous administration whereas a laxative should not be used continuously. (3) In that statements in the labeling which represented and suggested that it was an enzyme product and that when used as directed, it would balance the weight of the body, would be efficacious "for health," would supply a factor the absence of which causes many ailments to develop; would cause the glandular system to function properly and would restore energy and vigor; would prevent bacteria from forming toxic matter in the gastro-intestinal tract and would detoxify the system; that it was an adequate treatment for chronic angioneurotic edema, allergic eczema, pancreatic indigestion, allergic rhinitis, chronic allergic headache, allergic vomiting, chronic urticaria, allergic edema, allergic papular eczema, chronic allergic colitis, gastric and pancreatic achylia, acidosis, auto-intoxication, acne, appendicitis, bad breath, constipation, colitis, colds, catarrhal disease, gall bladder trouble, headache, neuritis, underweight, obesity, piles, rheumatism, stomach disorders, sluggishness, and spasmodic colon; that it was a preventive of catarrhal conditions of the sinuses, nose, ears, throat, bronchial tubes, lungs, stomach, liver, gall bladder, pancreas, intestines and colon, were false and misleading since it was not an enzyme product and would not be effective for the above-named diseases, symptoms, and conditions.

On June 18, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS *

DRUGS FOR HUMAN USE

766. Adulteration and misbranding of Adiron tablets; misbranding of Floramucin. U. S. v. Lawrence M. Williams (Lawrence Laboratories). Plea of guilty. Fine, \$250 and costs. (F. D. C. No. 5531. Sample Nos. 60557-E to 60560-E, incl.)

The Adiron tablets were deficient in vitamins A and D, and the labeling of Floramucin bore false and misleading statements.

On February 27, 1942, the United States attorney for the Northern District of Illinois filed an information against Lawrence M. Williams, trading as Lawrence Laboratories at Chicago, Ill., alleging shipment in interstate commerce within the

* See also Nos. 755, 756, 759, 762.